

Appl. No.: 10/038,398  
Amendment dated August 23, 2004  
Reply to Office Action of May 21, 2004

### **REMARKS/ARGUMENTS**

The office action of May 21, 2004 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1-8, 11-15 and 25-26 are pending in this application. Claims 9-10 and 16-24 have been withdrawn. Claims 8, 11 and 25 have been amended to more clearly point out and claim the present invention. Support for the amendments can be found in the claims as originally filed and throughout the specification. No new matter has been added.

#### **Claim Rejections Under 35 USC §112**

Claim 8 stands rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant accepts the examiner's assumption that the claim should read "wherein the polymer of the polymer-ceramic composition comprises. . ." and claim 8 is amended accordingly.

#### **Claim Rejections Under 35 USC §102**

Claims 1-6, 8 and 25-26 stand rejected under 35 USC § 102(e) as being anticipated by Lee et al., U.S. Patent No. 6,027,742. The rejection of these claims is respectfully traversed. Lee et al. do not disclose the invention as presently claimed. Reconsideration and withdrawal of these rejections is requested.

Amended Claim 1 is directed to a biocompatible implant for surgical implantation having a matrix comprising a thermoplastic-ceramic composition where the implant provides mechanical load-bearing support for natural bone structure for a predetermined amount of time to allow the natural bone structure to grow adjacent the material. The matrix has a pore size and porosity effective for enhancing bone growth. Claim 2 depends from claim 1 and further specifies that the natural bone structure substantially replaces the implant after a predetermined time. Claim 3 depends from claim 1 and further specifies that the matrix includes a polymeric

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material selected from the stated group of materials and combinations thereof. Claim 4 depends from claim 1 and further specifies that the implant includes a growth-enhancing composition. Claim 5 depends from claim 4 and further specifies that the resorbable material degrades upon implantation at a first rate to provide load-bearing support for a predetermined period of time and the growth-enhancing composition degrades upon implantation at a second rate faster than the first rate to stimulate new tissue growth. Claim 6 also depends from claim 4, further specifying that the growth-enhancing composition includes a biocompatible polymer-ceramic composition and a calcium source. Claim 8 depends from claim 6 and further specifies that the polymer of the polymer-ceramic composition is selected from the listed group and blend thereof. Amended claim 25 is directed to a method for repairing or replacing tissue by implanting a substrate that provides a foundation for new bone and tissue growth, as well as load-bearing support during such growth. Claim 26 depends from claim 25 and further specifies that the substrate is a resorbable material that degrades at a first rate to provide load-bearing support for a predetermined period of time and the growth-enhancing composition degrades at a second rate faster than the first rate to stimulate initial tissue growth on the substrate.

Lee et al. disclose a composite material comprising a strongly resorbable, poorly crystalline apatitic calcium phosphate cement and a biocompatible supplemental material in contact with the poorly crystalline material. Lee et al. disclose a composite that is a cement or paste. Lee et al. teach that the composite may be applied to bone-contacting surfaces of prosthetic devices, for use as a bone cement. It may be applied directly to bone defects as a filler. Lee et al. also teach that the composite may be used to fabricate fixtures or devices such as screws and plates or may also be used free standing in non-osseous (or non-bony) tissue. The composite of Lee et al. is not capable of providing mechanical load-bearing support for natural bone structure as in the present invention.

Lee et al. do not teach or suggest an implant that is able to provide mechanical load-bearing support for natural bone structure for a predetermined time to allow the natural bone structure to grow adjacent the material and thus fail to teach every element of the invention of claims 1-6, 8 and 25-26 as required under 35 U.S.C. § 102(e). Reconsideration and withdrawal of the rejection is respectfully requested.

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### **Claim Rejections Under 35 USC §103**

Claims 11-15 stand rejected under 35 USC §103(a) as being unpatentable over Lee et al. in view of Vyakarnam et al., U.S. Patent No. 6,534,084. This rejection is respectfully traversed, and reconsideration and withdrawal of the rejection is respectfully requested.

Amended claim 11 is directed to a biocompatible implant comprising a porous structure formed from a thermoplastic material and having porosity between about 25% to about 70% by volume, and a pore size between about 100 to about 2400  $\mu\text{m}$ . The biomedical implant further comprises a ceramic composition for enhancing the rate of bone growth, where the composition coats at least a portion of the structure or fills at least a portion of the pores of the structure. Claim 12 depends from claim 11 and further specifies that the thermoplastic material is a resorbable material that degrades at a first rate to provide load-bearing support for a predetermined period of time and the ceramic composition degrades at a second rate faster than the first rate to stimulate initial tissue growth on the implant. Claim 13 depends from claim 11 and further specifies that the structure has a porosity between about 50% to 60% by volume and a pore size between about 150 to about 400  $\mu\text{m}$ . Claim 14 depends from claim 11 and further specifies that the porous structure is selected from a group consisting of polymethylmethacrylate (PMMA), polybutylene-terephthalate (PBT), polyethyletherketone (PEEK), polyethyleneterephthalate (PET), high molecular weight polyethylene with hydrogel filling and combinations thereof. Claim 15 depends from claim 11 and further specifies that the ceramic composition includes a polymer and a calcium source.

Lee et al. do not disclose, teach or suggest the invention in amended claim 11 because, *inter alia*, it fails to disclose a specific porosity and pore size as specified in claim 11, as recognized in the Office Action. As disclosed previously, Lee et al. further does not disclose, teach or suggest the claimed invention because it fails to disclose, teach or suggest a structure that provides load-bearing support for natural bone structure.

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Vyakarnam et al. do not suggest the combination as claimed and do not cure the deficiencies in Lee et al. Vyakarnam et al. is directed to a method for the repair or regeneration of tissue where cells are contacted with foams that have a gradient in composition or microstructure. The cited section refers to a multilevel porous structure mimicking articular cartilage. The gradient foams and the stated pore size and porosity in Vyakarnam et al. are designed for tissue transition and interface zones and are not suitable for implants comprised of a thermoplastic material that provides load-bearing support for natural bone structures. One skilled in the art would not look to the disclosure in Vyakarnam et al. for when looking to form a porous structure from a thermoplastic material that provides load-bearing support for natural bone structure.

Thus, even if Lee et al. were combined with Vyakarnam et al., their combination would not result in the present invention as claimed. Accordingly, neither Lee et al. nor Vyakarnam et al., either alone or in combination, disclose, teach or suggest the invention of claims 11-15, and claims 11-15 are not obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. in view of Boltong, U.S. Patent No. 5,605,713. Claim 7 depends from claim 4, which depends from claim 1. As previously discussed, the present invention is directed to an implant for surgical implantation that provides mechanical load-bearing support for natural bone structure to allow the natural bone structure to grow adjacent the material. Claim 4 further specifies that the implant includes a growth-enhancing composition for stimulating new tissue growth at the site of implantation. Claim 7 further specifies that the growth-enhancing composition further comprises one or more transforming growth factors.

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As discussed above, Lee et al. do not disclose, teach or suggest the claimed invention because Lee et al. do not disclose, teach, or suggest an implant that provides mechanical load-bearing support for the natural bone structure to allow the natural bone structure to grow adjacent the material. Boltong does not provide any teachings to cure the deficiencies of Lee et al. Boltong discloses a process for the preparation of calcium phosphate cements. Further, Boltong is not directed to implants that provide mechanical load-bearing support. Thus, even if Boltong were combined with Lee et al., their combination would not result in the presently claimed invention. Further, Boltong teaches away from the present invention because Boltong teaches that the calcium orthophosphate cements may not be desirable for load supporting applications. Accordingly, neither Lee et al. nor Boltong, either alone or in combination, disclose, teach or suggest the invention of claim 7, and claim 7 is not obvious.

In view of the above, reconsideration and allowance of the pending claims are respectfully requested.

#### CONCLUSION

In view of the above remarks, prompt reconsideration and full allowance of the claims pending in the subject application are respectfully requested. As all rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same.

The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

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If the Examiner should have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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Dated: August 23, 2004

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